

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 2

In the Claims:

1. (Previously Presented) A method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:
immersing an intraluminal prosthesis comprising polymeric material in a mixture of a carrier fluid and a pharmacological agent;
pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the polymeric material; and
removing the pressure such that the carrier fluid diffuses out of the polymeric material and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material.
2. (Previously Presented) The method of Claim 1, wherein the carrier fluid is carbon dioxide.
3. (Original) The method of Claim 2, wherein the pharmacological agent comprises everolimus.
4. (Previously Presented) The method of Claim 1, wherein the carrier fluid is water.
5. (Original) The method of Claim 4, wherein pressurizing the mixture of carrier fluid and pharmacological agent comprises subjecting the mixture of carrier fluid and pharmacological agent to pressurized carbon dioxide.
6. (Original) The method of Claim 2, wherein the carbon dioxide is present in a supercritical state.
7. (Original) The method of Claim 6, wherein the carbon dioxide contains one or more of a co-solvent, a surfactant, and a co-surfactant.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 3

8. (Original) The method of Claim 1, wherein the carrier fluid is configured to alter diffusion coefficients of the polymeric material.
9. (Original) The method of Claim 8, wherein the co-solvent is selected from the group consisting of ethanol and methanol.
10. (Original) The method of Claim 1, wherein the intraluminal prosthesis is a stent.
11. (Original) The method of Claim 1, wherein the polymeric material is erodible.
12. (Original) The method of Claim 1, wherein the polymeric material is non-erodible.
13. (Original) The method of Claim 1, wherein the polymeric material is a coating on a portion of the intraluminal prosthesis.
14. (Original) The method of Claim 11, wherein the erodible polymeric material is selected from the group consisting of, surgical gut, silk, cotton, liposomes, poly(hydroxybutyrate), polycarbonate, polyacrylate, polyanhydride, polyethylene glycol, poly(ortho esters), poly(phosphoesters), polyesters, polyamides, polyphosphazenes, poly(*p*-dioxane), poly(amino acid), polyglactin, erodible hydrogels, collagen, chitosan, poly(lactic acid), poly(L-lactic acid), poly(D,L-lactic acid), poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly(D,L-lactic-co-glycolic acid), poly(ϵ -caprolactone), poly(valerolactone), poly(hydroxy butyrate), poly(hydrovalerate), polydioxanone, poly(propylene fumarate), poly(ethyleneoxide)-poly(butylene tetraphthalate), poly(lactic acid-co-lysine), poly(L-lactic acid) and poly(ϵ -caprolactone) copolymers.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 4

15. (Original) The method of Claim 1, wherein the step of removing pressure is carried out under controlled conditions.

16. (Original) The method of Claim 15, wherein the step of removing pressure is carried out under controlled conditions in which at least one parameter selected from the group consisting of temperature, rate of temperature change, pressure, rate of pressure change, carrier fluid quantity, and rate of carrier fluid quantity, is controlled in a predetermined pattern.

17. (Previously Presented) The method of Claim 1, further comprising:
immersing the intraluminal prosthesis in a mixture of a carrier fluid and radiopaque material; and
pressurizing the mixture of carrier fluid and radiopaque material for a time sufficient to cause the carrier fluid and radiopaque material to at least partially penetrate the polymeric material.

18. (Previously Presented) A method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:
immersing an intraluminal stent comprising erodible polymeric material in a mixture of carbon dioxide and pharmacological agent, wherein the erodible polymeric material is selected from the group consisting of, surgical gut, silk, cotton, liposomes, poly(hydroxybutyrate), polycarbonate, polyacrylate, polyanhydride, polyethylene glycol, poly(ortho esters), poly(phosphoesters), polyesters, polyamides, polyphosphazenes, poly(*p*-dioxane), poly(amino acid), polyglactin, erodible hydrogels, collagen, chitosan, poly(lactic acid), poly(L-lactic acid), poly(D,L-lactic acid), poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly(D,L-lactic-co-glycolic acid), poly(ϵ -caprolactone), poly(valerolactone), poly(hydroxy butyrate), poly(hydrovalerate), polydioxanone, poly(propylene fumarate), poly(ethyleneoxide)-poly(butylene tetraphthalate), poly(lactic acid-co-lysine), poly(L-lactic acid) and poly(ϵ -caprolactone) copolymers;
pressurizing the mixture of carbon dioxide and pharmacological agent for a time sufficient to cause the carbon dioxide and pharmacological agent to at least partially

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 5

penetrate the polymeric material; and

removing the pressure such that the carbon dioxide diffuses out of the polymeric material and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material.

19. (Original) The method of Claim 18, wherein the pharmacological agent is everolimus.

20. (Original) The method of Claim 18, wherein the polymeric material is a coating on a portion of the intraluminal prosthesis.

21. (Original) The method of Claim 18, wherein the carbon dioxide is present in a supercritical state.

22. (Original) The method of Claim 18, wherein the carbon dioxide is configured to alter diffusion coefficients of the polymeric material.

23. (Original) The method of Claim 18, wherein the intraluminal prosthesis is a stent.

24. (Previously Presented) A method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:

immersing an intraluminal prosthesis comprising erodible polymeric material in a mixture of water and a pharmacological agent, wherein the erodible polymeric material is selected from the group consisting of, surgical gut, silk, cotton, liposomes, poly(hydroxybutyrate), polycarbonate, polyacrylate, polyanhydride, polyethylene glycol, poly(ortho esters), poly(phosphoesters), polyesters, polyamides, polyphosphazenes, poly(*p*-dioxane), poly(amino acid), polyglactin, erodible hydrogels, collagen, chitosan, poly(lactic acid), poly(L-lactic acid), poly(D,L-lactic acid), poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly(D,L-lactic-co-glycolic acid), poly(ε-caprolactone), poly(valerolactone), poly(hydroxy butyrate), poly(hydrovalerate),

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 6

polydioxanone, poly(propylene fumarate), poly(ethyleneoxide)-poly(butylene tetraphthalate), poly(lactic acid-co-lysine), poly(L-lactic acid) and poly(ϵ -caprolactone) copolymers;

pressurizing the mixture of water and pharmacological agent with carbon dioxide for a time such that the water and pharmacological agent at least partially penetrate the polymeric material; and

removing the pressure such that the water diffuses out of the polymeric material and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material.

25. (Original) The method of Claim 24, wherein the polymeric material is a coating on a portion of the intraluminal stent.

26. (Original) The method of Claim 24, wherein the carbon dioxide is present in a supercritical state.

27. (Original) The method of Claim 26, wherein the carbon dioxide contains one or more of a co-solvent, a surfactant, and a co-surfactant.

28. (Original) The method of Claim 27, wherein the co-solvent is selected from the group consisting of ethanol and methanol.

29. (Original) The method of Claim 24, wherein the intraluminal prosthesis is a stent.

30. (Previously Presented) The method of Claim 24, further comprising:
immersing the intraluminal prosthesis in a mixture of a carbon dioxide and radiopaque material; and
pressurizing the mixture of carbon dioxide and radiopaque material for a time such that the carbon dioxide and radiopaque material at least partially penetrate the polymeric material.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 7

31. (Previously Presented) A method of impregnating an intraluminal prosthesis with a pharmacological agent, comprising:
placing an intraluminal prosthesis within a pressure vessel, wherein a portion of the intraluminal prosthesis comprises polymeric material;
pressurizing the interior of the pressure vessel to a predetermined pressure;
supplying a mixture of a carrier fluid and a pharmacological agent into the pressure vessel;
exposing the polymeric material and the mixture of carrier fluid and pharmacological agent in the pressure vessel for a time such that the carrier fluid and pharmacological agent at least partially penetrate the polymeric material; and
releasing the pressure in the pressure vessel such that the carrier fluid diffuses out of the polymeric material and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material.

32. (Previously Presented) The method of Claim 31, wherein the carrier fluid is carbon dioxide.

33. (Original) The method of Claim 32, wherein the pharmacological agent is everolimus.

34. (Previously Presented) The method of Claim 31, wherein the carrier fluid is water.

35. (Original) The method of Claim 31, wherein pressurizing the interior of the pressure vessel comprises pressurizing the interior of the pressure vessel with carbon dioxide.

36. (Original) The method of Claim 31, wherein the carbon dioxide is in a supercritical state.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 8

37. (Original) The method of Claim 36, wherein the carbon dioxide contains one or more of a co-solvent, a surfactant, and a co-surfactant.
38. (Original) The method of Claim 31, wherein the carrier fluid is configured to alter diffusion coefficients of the polymeric material.
39. (Original) The method of Claim 37, wherein the co-solvent is selected from the group consisting of ethanol and methanol.
40. (Original) The method of Claim 31, wherein the intraluminal prosthesis is a stent.
41. (Original) The method of Claim 31, wherein the polymeric material is erodible.
42. (Original) The method of Claim 31, wherein the polymeric material is non-erodible.
43. (Original) The method of Claim 31, wherein the polymeric material is a coating on a portion of the intraluminal prosthesis.
44. (Original) The method of Claim 41, wherein the erodible polymeric material is selected from the group consisting of, surgical gut, silk, cotton, liposomes, poly(hydroxybutyrate), polycarbonate, polyacrylate, polyanhydride, polyethylene glycol, poly(ortho esters), poly(phosphoesters), polyesters, polyamides, polyphosphazenes, poly(*p*-dioxane), poly(amino acid), polyglactin, erodible hydrogels, collagen, chitosan, poly(lactic acid), poly(L-lactic acid), poly(D,L-lactic acid), poly(glycolic acid), poly(D-lactic-co-glycolic acid), poly(L-lactic-co-glycolic acid), poly(D,L-lactic-co-glycolic acid), poly(ε-caprolactone), poly(valerolactone), poly(hydroxy butyrate), poly(hydrovalerate), polydioxanone, poly(propylene fumarate), poly(ethyleneoxide)-poly(butylene tetraphthalate), poly(lactic acid-co-lysine), poly(L-lactic acid) and poly(ε-caprolactone) copolymers.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 9

45. (Previously Presented) The method of Claim 31, further comprising:
immersing the intraluminal prosthesis in a mixture of a carrier fluid and
radiopaque material; and

pressurizing the mixture of carrier fluid and radiopaque material for a time
such that the carrier fluid and radiopaque material at least partially penetrate the polymeric
material.

46. (Original) A method of impregnating an intraluminal prosthesis with a
pharmacological agent, comprising:

exposing polymeric material of an intraluminal prosthesis to carbon dioxide
under conditions sufficient to tackify the polymeric material;

applying a pharmacological agent in micronized, dry form to the tackified
polymeric material; and

applying a membrane layer to the intraluminal prosthesis, wherein the
membrane layer is configured to allow the pharmacological agent to elute therethrough when
the intraluminal prosthesis is deployed within a body of a subject.

47. (Original) The method of Claim 46, wherein only selected portions of
the polymeric material of the intraluminal prosthesis are exposed to carbon dioxide and
become tackified.

48. (Original) The method of Claim 46, wherein the intraluminal
prosthesis is masked so as to limit exposure of the base layer to carbon dioxide to only
selected portions of the intraluminal prosthesis.

49. (Original) The method of Claim 46, wherein a plurality of
pharmacological agents are applied to the tackified polymeric material.

50. (Original) The method of Claim 49, wherein the plurality of
pharmacological agents comprises a uniform mixture.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 10

51. (Original) The method of Claim 46, wherein the pharmacological agent is applied by rolling the intraluminal prosthesis in a mass of the pharmacological agent.

52. (Original) The method of Claim 46, wherein the pharmacological agent is applied by blowing the dry, micronized particles onto the intraluminal prosthesis.

53. (Original) The method of Claim 46, wherein the membrane layer comprises ethylene vinyl acetate.

54. (Original) The method of Claim 46, wherein the membrane layer comprises polyethylene glycol.

55. (Original) The method of Claim 46, wherein the membrane layer comprises a fluoropolymer film.

56. (Original) The method of Claim 46, wherein the pharmacological agent comprises an antineoplastics.

57. (Original) The method of Claim 56, wherein the pharmacological agent comprises Paclitaxel.

58. (Original) A method of impregnating an intraluminal prosthesis with multiple pharmacological agents, comprising:

exposing polymeric material of an intraluminal prosthesis to carbon dioxide under conditions sufficient to tackify multiple portions of the polymeric material;

applying a respective different pharmacological agent in micronized, dry form to each respective tackified portion of the polymeric material; and

applying a membrane layer to the intraluminal prosthesis, wherein the membrane layer is configured to allow the pharmacological agents to elute therethrough when the intraluminal prosthesis is deployed within a body of a subject.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 11

59. (Original) A method of impregnating an intraluminal prosthesis with multiple pharmacological agents, comprising:

exposing polymeric material of an intraluminal prosthesis to carbon dioxide under conditions sufficient to tackify a portion of the polymeric material;

applying a first pharmacological agent in micronized, dry form to the tackified portion of the polymeric material;

applying a first membrane layer to the intraluminal prosthesis, wherein the first membrane layer is configured to allow the first pharmacological agent to elute therethrough when the intraluminal prosthesis is deployed within a body of a subject;

applying a second pharmacological agent to the first membrane layer; and

applying a second membrane layer to the intraluminal prosthesis such that the second pharmacological agent is sandwiched between the first and second membrane layers, and wherein the second membrane layer is configured to allow the second pharmacological agent to elute therethrough when the intraluminal prosthesis is deployed within a body of a subject.

60. (Original) An intraluminal prosthesis, comprising:

a tubular body portion comprising polymeric material;

a pharmacological agent in dry, micronized form attached directly to the tubular body portion; and

a membrane attached to the tubular body portion, wherein the membrane overlies the pharmacological agent, wherein the membrane is configured to allow the pharmacological agent to elute therethrough when the intraluminal prosthesis is deployed within a body of a subject.

61. (Original) The intraluminal prosthesis of Claim 60, wherein the membrane is configured to allow the pharmacological agent to elute at a predetermined rate.

62. (Original) The intraluminal prosthesis of Claim 60, wherein the tubular body portion comprises an organic-based, erodible material.

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 12

63. (Original) The intraluminal prosthesis of Claim 60, wherein the pharmacological agent is attached directly to the tubular body portion in only selected locations.

64. (Original) The intraluminal prosthesis of Claim 60, wherein a plurality of pharmacological agents are attached directly to the tubular body portion.

65. (Original) The intraluminal prosthesis of Claim 64, wherein the plurality of pharmacological agents are homogeneously distributed on the tubular body portion.

66. (Original) The intraluminal prosthesis of Claim 64, wherein the plurality of pharmacological agents are heterogeneously distributed on the tubular body portion.

67. (Original) The intraluminal prosthesis of Claim 60, wherein the membrane comprises ethylene vinyl acetate.

68. (Original) The intraluminal prosthesis of Claim 60, wherein the membrane layer comprises polyethylene glycol.

69. (Original) The intraluminal prosthesis of Claim 60, wherein the membrane comprises a fluoropolymer film.

70. (Original) The intraluminal prosthesis of Claim 60, wherein the tubular body portion comprises a first end, a second end, and a flow passage defined therethrough from the first end to the second end, wherein the body portion is sized for intraluminal placement within a subject passage, and wherein the body portion is expandable from a first, reduced cross-sectional dimension to a second enlarged cross-sectional dimension so that the body portion can be transported intraluminally to a targeted portion of a passage and then

In re: Williams *et al.*
Serial No. 10/662,757
Filed: September 15, 2003
Page 13

expanded to the second enlarged cross-sectional dimension so as to engage and support the targeted portion of the passage.

71. (Original) The intraluminal prosthesis of Claim 60, wherein the intraluminal prosthesis comprises a stent.